REMARKS

Prior to entry of this Amendment, Claims 1-73 were pending and under consideration. Claims 1-6 are indicated as being allowable and Claims 7-73 stand rejected. Applicant appreciates that its Amendment filed 11 January 2003 has been entered. With this Amendment, Claims 7-20 and 36-50 are being cancelled, without prejudice or disclaimer, and Claims 21, 23-24, 26-33, 53-54, 56-59, 62-64, 66-67 and 69-73 are being amended. No claims are being added. Thus, after entry of this Amendment, Claims 1-6, 21-35 and 51-73 are pending and under consideration.

I. Amendments of the Claims

Claims 7-20 and 36-50 have been cancelled, without prejudice against their reintroduction into this or one or more related applications, in order to reduce the issues going forward. In addition, Claims 21, 23-24, 26-33, 53-54, 56-59, 62-64, 66-67 and 69-73 have been amended.

Claim 21 has been amended in both the preamble and body. The preamble has been amended to read "A method of detecting the presence of a predetermined target nucleic acid sequence in a sample." This amendment is supported at, for example, Col. 11, lines 3-6 of the issued patent. The body has been amended to clarify the conditions under which the contacting is carried out and under which the recited probes specifically hybridize to the target sequence. Specifically, Claim 21 now recites that the contacting is carried out under conditions in which a FEN-1 polypeptide exhibits cleavage activity and that it is under such cleavage conditions that the 3'-region of the 5'-probe and the 5'-region of the 3'-probe are capable of specifically hybridizing to their respective portions of the target sequence. These amendments are supported by the text of the original patent at, for example, Col. 11, lines 6-8, 11-13 and 20-24, wherein it is taught that the sample and probes are incubated with a FEN-1 polypeptide and the release of nucleotides or polynucleotides (*i.e.,* cleavage) is detected.

Claim 1 has also been amended to recite that the 5'-probe, 3'-probe and target sequence hybridize with one another to form a 5',3'-double flap structure that is cleavable by a FEN-1

polypeptide. Support for this amendment is discussed in detail in connection with the rejection under 35 U.S.C. § 251.

Claim 59, although directed to a kit, has been amended in a manner similar to Claim 21. In addition, the preamble of Claim 59 has been amended to recite "a kit for use in ....". The amendments of Claim 59 are supported by the sections pointed out in connection with Claim 21.

Claims 23-24, 53-54 and 66-67 have been amended to clarify the region of the 5'-probe that contains the detectable label.

Claims 26-27 and 69-70 have been amended to recite that the FEN-1 polypeptide is encoded by polynucleotides corresponding in scope with the polynucleotides of Claims 2 and 3, respectively.

Claims 28-30 have been amended to depend from Claim 21 instead of Claim 26 to maintain proper antecedent basis in light of the amendment of Claim 26.

Claims 31-32, 56-57 and 62-63 have been amended to recite the region of the 3'-probe that contains the stated number of nucleotides. Claims 33, 58 and 64 have been amended to recite the region of the 5'-probe that contains the stated number of nucleotides. Support for these amendments is discussed in more detail in connection with the rejection of these claims under 35 U.S.C. § 112, ¶ 1.

Lastly, Claims 71-73 have been amended for clarity and to multiply depend from Claims 59-68. These amendments were necessitated by the amendment of Claim 69.

For reasons outlined above, or that will be discussed in more detail below, none of these amendments present new matter under 35 U.S.C. § 251. Entry into the application is therefore requested.

II. Rejection of Claims 7-73 Under 35 U.S.C. § 251

Claims 7-73 stand rejected under 35 U.S.C. § 251 as being based upon new matter for which reissue is sought. According to the Patent Office, neither the issued patent nor the

properly incorporated Harrington & Lieber ("H&L") article provide support for these claims. The rejection is moot as applied to cancelled Claims 7-23 and 36-50 and traversed as applied to pending Claims 21-35 and 51-73.

As an initial matter, Applicant is concerned that the Patent Office has misunderstood its prior remarks regarding the incorporation by reference of the H&L article. Applicant is also concerned that the Patent Office's treatment of two distinct issues under 35 U.S.C. § 251 as though they are a single issue has resulted in unnecessary confusion. Accordingly, before addressing the substance of the rejection, Applicant will attempt to clarify the situation.

A. Amendments of a Disclosure and Amendments of Claims Raise Distinct Issues Under 35 U.S.C. § 251

Concurrently with the filing of the instant reissue application, Applicant submitted a Preliminary Amendment amending the disclosure and claims of the application. Although both of these types of amendments raise potential issues of "new matter" under 35 U.S.C. § 251, the issues are distinct. *See, e.g., In re Rasmussen*, 211 USPQ 323 (CCPA 1981), especially at page 326, where, in the context of the related statutory provision prohibiting entry of new matter into original (*i.e.*, non-reissue) applications, the court notes the same confusion present in the instant application:

> As illustrated in the present case, employment of §§ 132 and 112 as interchangeable leads to confusion of *two distinct concepts*: (1) the adding of new matter to the disclosure; and (2) the broadening of a claim. (Emphasis added)

See also, In re Rasmussen, 211 USPQ at page 326 notes 5 and 6, confirming that the same logic applies to new claims and to "new matter" issues under 35 U.S.C. § 251.

B. The Amendments of the Disclosure Inserting the Actual Text and Figures of the Incorporated Harrington & Lieber Article Do Not Introduce New Matter Under 35 U.S.C. § 251

Pursuant to 35 U.S.C. § 251, amendments to the disclosure of reissue application must not introduce new matter into the application. As established previously on the record, matter that does not appear explicitly in an application but that is nonetheless implicitly a part

thereof by virtue of an incorporation by reference is not "new." Consequently, the actual text (and figures) of an incorporated reference may be explicitly amended into the description of a reissue application without violating 35 U.S.C. § 251.

Applicant's amendment to *the description* did just that. It inserted explicitly into the disclosure of the reissue application the actual text and figures of the incorporated Harrington & Lieber ("H&L") article. To establish the propriety of this amendment, Applicant relied on cases such as *In re Voss* to demonstrate that the specific references in the description of the application to the H&L article properly incorporated its contents therein.

Both the prior Office Action and the instant Advisory Action appear to acknowledge that this particular amendment– the amendment of *the disclosure* inserting the actual text and figures of the incorporated H&L article– is proper.[1/] If this is not the case, Applicant requests clarification so that it can better understand the outstanding issues going forward.

C. Claims 7-73 Do Not Introduce New Matter Under 35 U.S.C. § 251 Because They Are Supported By the Original Disclosure In the Manner Prescribed By 35 U.S.C. § 112, ¶ 1

In addition to the disclosure, the Preliminary Amendment also amended *the claims* of the instant reissue application, adding Claims 7-73. Applicant pointed out that Claims 7-73 did not present new matter under 35 U.S.C. § 251 because they were *supported by* the disclosure of the application as originally filed. Applicant has *never* represented to the Patent Office that the language of Claims 7-73 derives *ipsis verbis* from the text of the incorporated H&L article. Nor did Applicant, as asserted by the Patent Office in the Advisory Action, ignore

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[1/] In the Advisory Action, the Patent Office states the following:

> By Applicant's own argument, it is acknowledged that replacing subject matter incorporated into an application by reference with the actual text and figures of the incorporated document do not constitute new matter. Therefore incorporation of the actual text or figures from [the H&L article] would be proper.

Advisory Action at paragraph bridging pages 2 and 3 (emphasis in original removed). In addition, in the first full paragraph at page 3 of the Advisory Action, the Patent Office refers to the H&L article as "the properly incorporated reference."

the sentence following the Patent Office's assertion that "incorporation of the actual text or figures from Harrington and Lieber [citation omitted] would be proper." Rather, to demonstrate that Claims 7-73 did not violate 35 U.S.C. § 251, Applicant articulated the legal standard by which *amendments of claims* are assessed under 35 U.S.C. § 251. In sum, Applicant argued the following:

> (1) that the issue of whether amended or new *claims* in a reissue application run afoul of the "new matter" prohibitions of 35 U.S.C. § 251 is assessed by determining whether the new claims are adequately supported by the disclosure of the patent as originally filed ("original disclosure") in the manner prescribed by 35 U.S.C. § 112, ¶ 1;
>
> (2) that amended or new claims in a reissue application are adequately supported under 35 U.S.C. § 112, ¶ 1 when the original disclosure reasonably conveys to skilled artisans that the inventor invented the subject matter of the amended or new claims; and
>
> (3) that by virtue of an incorporation by reference, the original disclosure of the instant reissue application that can be relied upon for written description support under 35 U.S.C. § 112, ¶ 1 includes not only the actual text of the issued patent, but also the text and figures of the incorporated H&L article (and any other incorporated references).

In fact, the only reason the incorporation by reference was discussed at all in connection with Claims 7-73 was to establish that the text and figures of the incorporated H&L article could be relied upon for purposes of establishing that the original disclosure adequately supported Claims 7-73 under 35 U.S.C. § 112, ¶ 1, and hence 35 U.S.C. § 251.

Given this context, Applicant finds the Patent Offices repeated insistence that "effective incorporation" is lacking with respect to Claims 7-73 both improper and confusing. As Applicant amply established in its prior response, amendments of *claims* in a reissue application do not run afoul of the new matter prohibitions of 35 U.S.C. § 251 when the amended claims are supported by the original disclosure in the manner prescribed by 35 U.S.C. § 112, ¶ 1. The Federal Circuit has recently pointed this out in the context of the related "new matter" prohibition for original (*i.e.*, non-reissue) applications under 35 U.S.C. § 132:

> Although the statute proscribes addition of new matter to a specification or claims under 35 U.S.C. § 132, the United States Court of Customs and Patent Appeals decided to police the addition of new matter to claims separately using § 112. This court's predecessor explained that the use of § 132 or § 112 was synonymous because "a rejection of an amended claim under § 132 is equivalent to a rejection under § 112, first paragraph. Since then, this court has continued to use § 112 to ensure that a patentee had possession at the time of filing of subject matter subsequently claimed.

Moba v. Diamond Automation, Inc., 66 USPQ2d 1429, 1438 (Fed. Cir. 2003) (citations omitted).

Thus, in the context of Claims 7-73, the "incorporation by reference" issue is a red herring. It is only relevant to the extent it helps define the contents of the original disclosure that can be relied upon for written description support under 35 U.S.C. § 112, ¶ 1.

D. Methods and Kits Utilizing 3'-Polynucleotide Probes Are Described in the Original Disclosure

The Advisory Action states that the crux of the rejection is directed to the inclusion of a 3'-polynucleotide probe in the various claimed methods, complexes and kits.[2/] According to the Patent Office, while the text of the issued patent relied upon by Applicant (Col. 11, lines 3-48 and Col. 42, line 63 through Col. 43, line 36) describes the method steps using a 5'-polynucleotide probe, there is no mention of a 3'-polynucleotide probe. It further alleges that flap length ranges of 1-10 or 1-20 nucleotides are not taught. Applicant disagrees.

At Col. 11, lines 3-11, the patent teaches that, in one aspect, the invention provides a novel diagnostic assay that utilizes a probe polynucleotide capable of specific hybridization to all or a portion of a target polynucleotide which forms, as a result of the hybridization, a 5'-flap structure that can be cleaved by a FEN-1 polypeptide. At Col. 11, lines 17-20, it is taught that

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[2/] At page 3 of the Advisory Action, the Patent Office repeats rejections from the final Office Action without further elaboration or discussion of Applicant's prior responses thereto. Since the Advisory Action specifically points out that the real issue is the inclusion of a 3'-polynucleotide probe (Advisory Action at page 4), and fails to identify any deficiencies in Applicant's responses to these rejections, Applicant assumes these rejections have been withdrawn. If this is not the case, Applicant requests clarification regarding why its prior remarks are insufficient to overcome the rejections.

this probe polynucleotide comprises two portions: a first portion which hybridizes to the target sequence and a second portion which is adjacent to the first portion and which forms the unhybridized flap portion. This is the "5'-polynucleotide probe" to which the Patent Office refers.

The patent then goes on to teach that *"frequently an adjacent polynucleotide is present* which hybridizes to the portion of the target polynucleotide immediately 5' to the portion of the target which hybridizes to the probe polynucleotide sequence." Col. 11, lines 20-24 (emphasis added). This teaching is repeated at Col. 43, lines 15-19 and exemplified with reference to the non-limiting embodiment illustrated in FIG. 6 (see Col. 43, lines 25-29). This adjacent polynucleotide, labeled "Fadj strand" in FIG. 6, is an embodiment of a 3'-polynucleotide probe. Given this clear teaching, Applicant does not understand on what basis the Patent Office concludes that a 5'-polynucleotide probe, but not a 3'-polynucleotide probe, is taught.

The specific 3'-polynucleotide probes recited in amended Claims 21-35 and 51-73 are taught in the incorporated H&L article. Specifically, FIG. 5 of the incorporated H&L article, as well as its associated text, teach that this 3'-polynucleotide probe (or Fadj strand) can include a 3'-unhybridized flap region.

E. 3'-Flap Lengths of 1-10 Nucleotides and 5'-Flap Lengths of 1-20 Nucleotides Are Described in the Original Disclosure

The Patent Office also contends that 3'-flap lengths of 1-10 or 1-20 nucleotides are not taught. First, Applicant notes that none of the pending claims recite 3'-flaps that are 1-20 nucleotides in length. This length range is recited for *5'-flaps*. Applicant believes the amendments of Claims 31-33, 56-58 and 62-64 are consistent with this point.

Second, Applicant explicitly addressed this same rejection at pages 10-11 of their prior Amendment. The Patent Office has failed to explain *why* it considers the support identified by Applicant inadequate. In the 5',3'-double flap structures of the incorporated H&L article, the 3'-probe has a flap region that is 1 nucleotide (Double Flap #1 in FIG. 5 at page 4506) or 10 nucleotides (Double Flap #2 in FIG. 5 at page 4506) in length. Both of these double flap structures are cleaved. From this, it is concluded that the 3'-probe is only required to create a

double-stranded region next to the elbow of the 5'-flap strand (rather than to supply a 3'-terminus), and that this 3'-probe can optionally include a 3'-flap of variable length (see H&L article at page 4506, Col. 2, lines 3-20). These "3'-flaps" correspond to the 3'-region of the recited 3'-polynucleotide probe. The description of two exemplary 3'-probes having 3'-regions that are 1 and 10 nucleotides in length, coupled with the disclosure teaching that the length of this 3'-region can vary, is a description of a 3'-region that is from 1 to 10 nucleotides in length, as recited in amended Claims 31-32, 56-57 and 62-63.

Amended Claims 33, 58 and 64, which specify that the 5'-probe has a 5'-region that is 1-20 nucleotides in length, are likewise supported by the original disclosure. The 5'-flaps of the cleavable substrates described in the original disclosure vary from 1 nucleotide, to 5 nucleotides, to 20 nucleotides in length (*see*, Col. 46, lines 46-58 and H&L article at page 4506, FIG. 5, Double Flaps #1 and #2). Moreover, it is specifically taught that cleavage of the 5'-flap is independent of its length (Col. 19, lines 21-22). The 5'-region of the 5'-probe corresponds to the 5'-flap. Accordingly, amended Claims 33, 58 and 64 are supported by the original disclosure.

F. The Recited 5',3'-Double Flap Structures Are Cleaved By FEN-1 Polypeptides

Lastly, the Patent Office notes that the issued patent teaches that a 3'-flap structure was not cleaved by a FEN-1 polypeptide (*see* Col. 46, lines 65-67), and concludes from this teaching that 3'-flap structures are unsuitable for use in the presently claimed methods. Applicant concurs that the teaching at Col. 46, lines 65-67 indicates 3'-flaps are not cleaved by FEN-1 polypeptides. However, the relevance of this teaching to the pending claims is not apparent.

The pending claims do not recite 3'-flap structures. Rather, they recite *5', 3'-double flap* structures. Binding and cleavage of such double-flap structures by a FEN-1 polypeptide is taught throughout the incorporated H&L article at, for example, FIG. 5 and its associated text (see H&L at page 4605). Thus, the recited structures are clearly suitable for use in the claimed methods.

G. All Claims of the Instant Reissue Application Satisfy 35 U.S.C. § 251

In summary, Applicant submits amended Claims 21-35 and 51-73 do not introduce new matter into the instant reissue application. Claims presented in a reissue application do not constitute new matter under 35 U.S.C. § 251 when the claims are supported by the original disclosure in the manner prescribed by the first paragraph of 35 U.S.C. § 112. *In re Rasmussen,* 211 USPQ at 326; *Moba v. Diamond,* 66 USPQ2d at 1438. The written description requirement of § 112 is satisfied when the disclosure, considered as a whole, reasonably conveys to skilled artisans that the inventor invented the subject matter claimed. *See, e.g., Ralston Purina Co. v. Far-Mar-Co Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985); *Vas-Cath v. Mahurkar,* 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). *Ipsis verbis* description is not required. *Fujikawa v. Wattanasin*, 39 UPPQ2d 1895, 1904 (Fed. Cir. 1996). Nor must every nuance of the claims be explicitly described. *In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996) ("If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is satisfied.").

The original disclosure satisfies this legal standard for amended Claims 21-35 and 51-73. Applicant has pointed out in prior responses, with the aid of tables specifying exact pages and line numbers where pertinent disclosure could be found, that the original disclosure describes each and every feature of amended Claims 21-35 and 51-73. Applicant has pointed out above where in the original disclosure 3'-polynucleotide probes and 3'- and 5'-flaps of specified lengths are taught. As such, the original disclosure reasonably apprises skilled artisans that Applicant invented the subject matter of amended Claims 21-35 and 51-73. This is all that 35 U.S.C. § 251 demands.[3/] Accordingly, Applicant requests that the rejection of Claims 7-73 under 35 U.S.C. § 251 be withdrawn.

[3/] Applicant notes that Claims 7-73 as originally presented in the Preliminary Amendment did not introduce new matter under 35 U.S.C. § 251 for these same reasons.

III. Rejection Under the Written Description Clause of 35 U.S.C. § 112, ¶ 1

Claims 7-10, 14-27, 31-44 and 48-70 stand rejected under 35 U.S.C. § 112, ¶ 1 as allegedly lacking written description support in the original disclosure. The rejection is moot as applied to cancelled Claims 7-10, 14-20 and 36-49, and traversed as applied to amended Claims 21-27, 31-35 and 59-70.[4/]

A. The Methods and Kits of Claims 21-27, 31-35 and 59-70, Including the FEN-1 Polypeptides Recited Therein, Are Adequately Described In the Original Disclosure

1. The Operational Steps Recited in Method Claims 21-27 and 31-35 Are Adequately Described In the Original Disclosure

First, the Patent Office alleges the rejected claims lack written description support because they do not contain any limitations defining the structures of "the claimed endonuclease . . . ." The basis of this rejection is rooted in the Federal Circuit's decision *The Regents of the University of California vs. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), a case involving what description is adequate to support claims drawn to a genus of cDNA molecules (or a genus of polypeptide molecules). However, as Applicant has pointed out on several prior occasions, none of the rejected claims are directed to endonucleases *per se*. Recognition of this fact is important, because it is the *claimed invention* that must be adequately supported by the disclosure under 35 U.S.C. § 112, ¶ 1. *See, e.g., In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989).

As discussed in connection with the rejection under 35 U.S.C. § 251, *supra,* the test for compliance with the written description requirement of 35 U.S.C. § 112, ¶ 1 is whether the disclosure, viewed as a whole, conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicant was in possession of the claimed invention. *See, Vas-*

[4/] Rejected Claims 51-58 are directed to a hybridization complex formed between three polynucleotides. Arguments directed to these claims were presented in Applicant's prior response. Since the Patent Office's reasoning supporting the instant rejection appears to be irrelevant to Claims 51-58 (they do not mention endonucleases), and the Patent Office has neither specifically reiterated the prior rejection nor addressed why Applicant's prior remarks were insufficient to overcome the rejection, Applicant believes Claims 51-58 were inadvertently included in the instant rejection. If this is not the case, clarification of the outstanding rejection is requested.

Cath, 19 USPQ2d at 1116. As recently pointed out by the Federal Circuit, "the *Lilly* disclosure rule does not require a particular form of disclosure . . . ." *Moba,* 66 USPQ2d at 1439. As long as one of skill in the art could determine from the disclosure that the inventor possessed the invention at the time of filing, 35 U.S.C. § 112, ¶ 1 is satisfied. *Id.*

Amended Claims 21-27 and 31-35 are directed to a *method* of detecting the presence of a target nucleic acid sequence in a sample that involves forming and cleaving a 5',3'-double flap structure. A method claim is a series of operational steps that may be carried out by any means. It is *the series of operations* that must be adequately described, not the apparatus for carrying out each step of the method.

This point was recently clarified by the Federal Circuit in *Moba v. Diamond,* 66 USPQ2d 1429 (Fed. Cir. 2003). In *Moba,* an accused infringer argued that a patent claim directed to a method of sorting eggs involving lifting eggs from a moving conveyor lacked written description support under 35 U.S.C. § 112, ¶ 1 because the patent specification did not disclose the conveyor mechanism. The Federal Circuit disagreed. In so doing, the court reiterated that the legal standard for compliance with the written description requirement is the standard articulated by Applicant above, and found that the patent disclosure described every element of the claim in sufficient detail to satisfy the requirement. *See Moba,* 66 USPQ2d at 1439. Since the *method, i.e.,* the series of operational steps, was described in detail sufficient for one of skill in the art to ascertain that the inventor was in possession of the claimed method, it did not matter that one of the apparatuses used to carry out the method—the conveyor mechanism—was neither disclosed nor described.

In connection with the rejection under 35 U.S.C. § 251, Applicant has on several occasions pointed out, with the aid of tables listing page and line numbers, where in the original disclosure the series of operational steps of method Claims 21-27 and 31-35 are adequately described. This is all the written description clause of 35 U.S.C. § 112, ¶ 1 requires.

2. The Kits Recited in Claims 59-70 Are Drawn to A Combination of Elements

Amended Claims 59-70 are directed to kits for use in detecting the presence of a target nucleic acid sequence which comprise a FEN-1 polypeptide and two polynucleotide probes. Although these claims include a FEN-1 polypeptide as one of their components, Applicant is not required to limit these claims to specific FEN-1 polypeptide sequences. These kit claims are not directed to the FEN-1 polypeptides *per se*. Rather, they are directed to *a combination of elements*, one of which is a FEN-1 polypeptide. The novelty of the claims does not reside in the FEN-1 polypeptide, but rather in the *combination* of the recited elements. The Patent Office has cited no authority to support its position that these claims must be limited to specific FEN-1 polypeptide sequences. In contrast, the courts have consistently approved such "functional" language in claims to combinations of elements. See, e.g., *In re Herschler,* 200 USPQ 711 (CCPA 1979); *In re Halleck,* 164 USPQ 647 (CCPA 1970); *In re Fuetterer,* 138 USPQ 217 (CCPA 1963); *In re Boller,* 141 USPQ 740 (CCPA 1964). The Patent Office has failed to explain why these cases do not apply to amended Claims 59-70.

3. The Original Disclosure Describes Species Representative of the FEN-1 Polypeptide Genus

Moreover, Applicant has pointed out eight exemplary species of FEN-1 polypeptides that are specifically described in the original disclosure in accordance with the guidance provided by the Written Description Guidelines (Federal Register 66(4):1092-1111 (January 5, 2001) at page 1106) and *The Regents* decision: the human FEN-1 of SEQ ID NO:1, the mouse FEN-1 of SEQ ID NO:3, the yeast FEN-1 of SEQ ID NO:5, the Δrad2 of SEQ ID NO:7 and the various FEN-1 enzymes found in extracts from calf thymus, rabbit reticulocytes, Chinese hamster fibroblasts and Drosophila embryos (for these latter FEN-1 species see Col. 44, lines 23-27). Without supplying any reasoning whatsoever, the Patent Office summarily concludes that these eight exemplary species are not representative of the FEN-1 polypeptide genus, and are therefore inadequate to support the rejected claims.

Applicant reminds the Patent Office that once rebuttal evidence or arguments have been presented, the Patent Office must not only reassess the *whole record,* but also *fully respond* to the rebuttal evidence and/or arguments:

> Upon reply by applicant, before repeating any rejection under 35 U.S.C. § 112, ¶ 1, for lack of written description, review the basis of the rejection *in view of the record as a whole,* including amendments, arguments and evidence submitted by application. * * * If the record still does not demonstrate that the written description is adequate to support the claims, repeat the rejection under 35 U.S.C. § 112, ¶ 1, *fully respond to applicant's rebuttal arguments,* and properly treat any further showings by applicant in the reply.

MPEP § 2163IIIB (emphasis added). Summarily concluding that eight exemplary species are not representative of the FEN-1 polypeptide genus, without more, falls far short of the mark. As required by the MPEP, the Patent Office must explain *why* a description of eight exemplary species spanning myriad different life forms (yeast, insect, rabbit, hamster, mouse, cow, human) is inadequate, especially given the fact that the rejected claims are directed to methods of use and kits, and not to the FEN-1 polypeptide molecules *per se.*

Recently, the Federal Circuit *declined* to find *three* deposited species– far fewer than the eight highlighted by Applicant– legally insufficient to adequately support generic claims to nucleic acid molecules. *See Enzo Biochem Inc. v. Gen-Probe Inc.,* 63 USPQ2d 1609, 1615 (Fed. Cir. 2002). Rather, the court sent the issue back to the lower court to determine whether one of skill in the art would consider the generic claims to be adequately described in light of the three deposited species. The court explicitly noted that the three species may be representative of the genus. *Enzo Biochem,* 63 USPQ2d at 1615 ("If those sequences are representative of the scope of the genus, *i.e.,* if they indicate that the patentee has invented species sufficient to constitute the genera, they may be representative of the scope of those claims."). Given that *three* species may be adequate to support a generic claim to molecules *per se*, Applicant queries why the exemplary *eight* species it highlighted are inadequate to support claims drawn to methods of use and kits.

4. Claims 21-27, 31-35 and 59-70 Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶ 1

Applicant submits amended Claims 21-27, 31-35 and 59-70 satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1. All of the steps of amended method Claims 21-35, as well as the 5',3'-double-flap substrates and FEN-1 polypeptides necessary for carrying out the claimed steps, are described in the original disclosure. Indeed, at least *eight* species of FEN-1 polypeptides suitable for carrying out the claimed method are described. Likewise, the probes and FEN-1 polypeptides comprising the kits of amended Claims 59-70 are described in the original disclosure. The original disclosure therefore reasonably apprises skilled artisans that Applicant was, at the time the original application was filed, in possession of the inventions recited in amended Claims 21-27, 31-35 and 59-70.

B. The 5',3'-Double Flap Structures Are Adequately Described In the Original Disclosure

The Patent Office also appears to be levying a new rejection against at least method Claims 21-27 and 31-35. Previously, the Patent Office's concern about lack of structure was directed to the structure of the FEN-1 endonuclease. Now, the Patent Office alleges these claims offend the written description requirement owing to a perceived deficiency in the description of the 5',3'-double flap structure:

> Likewise in the instant case, claims drawn to a method of cleaving a 5'-polynucleotide by FEN-1 does not functionally or structurally define the double flap structure used as substrates in the method [nor are structures well known in the art prior to the instant filing], for being acted upon by the FEN-1 polypeptide, and that the determination of suitable substrates or double flap structures would require testing by trial and error many known or unknown double flap structures to ascertain those which would function in the manner required by the claims, and would unduly burden those skilled in the art.

Advisory Action at page 7 (emphasis in original).

The basis of this rejection lies in a quotation taken from *In re Fuetterer* summarizing the board's reasoning underlying its affirmation of one of the rejections at issue in the case:

> * * * There is no indication that the function asserted for the salts is known in the art so that the suitable salts could be readily determined without undue experimentation nor is there any criteria given in the disclosure by which it could be fairly readily determined what salts are suitable. It seems that the determination of suitable salts thus would require testing by trial and error many thousands of known salts to ascertain those which would function in the manner required by the claims, and such a burden should not be required of the public or even by those skilled in the art. Accordingly, we will sustain this rejection.

Advisory Action at page 7. However, Applicant notes this language is quoted by ***the dissent*** in the *In re Fuetterer* decision. *See*, *In re Fuetterer*, 138 USPQ at 223. The *majority* expressly found the board's quoted reasoning irrelevant, and overturned the rejection it had affirmed:

> We find the arguments of the board and examiner relating to experimentation necessary to determine the suitability of *undisclosed* salts to operate in appellant's claimed combination beside the point. Appellant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloidal suspending properties. We see nothing in the patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination.

In re Fuetterer, 138 USPQ at 223 (emphasis in original). It is unclear to Applicant how reasoning that was expressly rejected by the CCPA forms a proper basis for a rejection.

C. Applicant Is Not Required To Recite Where the Cleavage Occurs

Second, the Patent Office contends Claims 7-10, 14-27, 31-44 and 48-70 lack adequate written description because they allegedly do not contain any limitations that define the strand that the FEN-1 polypeptide uses as a substrate. Applicant does not understand this rejection. Amended Claims 21-27 and 31-35 recite a method of determining the presence of a target nucleic acid sequence in a sample that involves contacting the target with two probes that hybridize to adjacent portions of the target to form a 5',3'-double-flap structure, and a FEN-1

polypeptide that cleaves the structure. Amended Claims 59-70 are directed to kits comprising a FEN-1 polypeptide and two probes. The probes are able to specifically hybridize to a target nucleic acid sequence to form a double-flap structure that can be cleaved by the FEN-1 polypeptide. All of these claims are operative as claimed. *How* they work, *i.e.,* which strand gets cleaved by the FEN-1 polypeptide is irrelevant. Applicant is not required to recite in their claims *how* their claimed inventions work. In fact, Applicant is not even required to *know* how they work. *See, e.g., Newman v. Quigg*, 49 USPQ2d 1340 (Fed. Cir. 1989). It is sufficient that they do.[5/]

D. All Claims Satisfy the Written Description Requirement of 35 U.S.C. § 112, ¶ 1

Accordingly, for the reasons discussed above, Applicant submits amended Claims 21-27, 31-35 and 59-70 satisfy the written description clause of 35 U.S.C. § 112, ¶ 1. All of the steps of method Claims 21-27 and 31-35, as well as the 5',3'-double-flap substrates and FEN-1 polypeptides necessary for carrying out the claimed method, are described in the original disclosure. At least *eight* species of FEN-1 polypeptides suitable for carrying out the claimed method are described. Likewise, the probes and FEN-1 polypeptides comprising the kits of amended Claims 59-70 are described in the original disclosure. The original disclosure therefore reasonably apprises skilled artisans that Applicant was, at the time the original application was filed, in possession of the inventions recited in amended Claims 21-27, 31-35 and 59-70.[6/] That is all that the written description clause of 35 U.S.C. § 112, ¶ 1 demands. Accordingly, Applicant requests that the rejection of Claims 7-10, 14-27, 31-44 and 48-70 for lack of written description be withdrawn.

[5/] In connection with the rejection, the Patent Office notes, "FEN-1 cleavage is flap strand specific and independent of flap length." Advisory Action at page 5. What this strand specificity has to do with the rejection is unclear to Applicants. Given an appropriate substrate, such as the 5',3'-double flap substrate, the FEN-1 polypeptide will cleave the structure. If an appropriate structure does not form, cleavage will not occur. Applicant is aware of no authority, and the Patent Office has cited none, indicating that Applicant must recite in its claims where the cleavage occurs.

[6/] It is noted that Claim 7-73 as originally presented in the Preliminary Amendment satisfy the written description clause of 35 U.S.C. § 112, ¶ 1 for these same reasons.

IV. Rejection Under the Enablement Clause of 35 U.S.C. § 112, ¶ 1

Claims 7-73 stand rejected under 35 U.S.C. § 112, ¶ 1 as being allegedly non-enabled. The rejection is moot as applied to cancelled Claims 7-20 and 36-50 and traversed as applied to amended Claims 21-35, 51-58 and 59-73.

The Patent Office alleges that in order for Claims 21-35, 51-58 and 59-73 to be enabled, they must include specific hybridization conditions because:

> [w]ithout a clear and explicit recitation of the conditions that were actually used by Applicants *in isolating the claimed polynucleotides which hybridize to the disclosed sequences,* the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention.

Advisory Action at page 8, lines 14-17 (emphasis supplied). This statement, and in particular the emphasized passage, completely mischaracterizes the inventions recited in Claims 21-35, 51-58 and 59-73. It is also completely irrelevant. Claims 21-35, 51-58 and 59-73 are not directed to isolated polynucleotide molecules *per se*. In particular, they are not directed to isolated polynucleotide molecules whose novelty is defined by their ability to hybridize to specified sequences.

A. Method Claims 21-35 Are Fully Enabled

Amended Claims 21-35 are directed to *methods* that utilize polynucleotide probes that hybridize to a target sequence to form a specific structure, a 5',3'-double flap structure (*see, e.g.,* FIG. 5 at page 4506 of the incorporated H&L article), that can be specifically bound and cleaved by a FEN-1 polypeptide. Neither the recited probes nor target are "isolated polynucleotides" of the type referred to by the Patent Office. Rather, the target may be *any* nucleic of interest, and the probes are designed to have sequences capable of forming a 5',3'-double flap structure when hybridized to the target.

To clarify that Claims 21-35 have nothing to do with "isolated polynucleotides" of the type referred to by the Patent Office, Applicant has amended these claims to indicate that the

target nucleic acid comprises a predetermined sequence of interest, and that the sequences of the 5'- and 3'-probes are defined by their ability to specifically hybridize to specified regions of this sequence. The predetermined sequence could be *any* sequence. Claims 21-35 have also been amended to clarify that the relevant conditions under which the probes must be capable of specifically hybridizing to their respective portions of the target sequence are the conditions of the assay, *i.e.,* conditions under which the FEN-1 polypeptide exhibits cleavage activity.

In their prior response, Applicant noted that the original disclosure teaches cleavage conditions that actually work, citing as specific examples Col. 39, line 65 through Col. 40, line 18, and the incorporated H&L article.[7/] The Patent Office points out that no specific pages of the H&L article were cited. Applicant regrets this oversight and directs the Patent Office to page 4504 of the H&L article. Conditions suitable for carrying out FEN-1 cleavage are provided in the first full paragraph bridging the first and second columns of this page. Cleavage of 5',3'-double flap structures carried out using these conditions is taught in the legend to FIG. 5 (at page 4506).

The Patent Office also contends no specific conditions are taught at the following sections noted by Applicant: Col. 39, line 65 through Col. 40, line 18 and Cols. 49-51. Regarding the former cite, Applicant directs the Patent Offices attention to Col. 40, lines 5-7. Regarding the latter cite, see especially the assay conditions taught at Col. 49, line 62-65; Col. 50, lines 28-31.

Although specific cleavage conditions are taught in the disclosure, Applicant is not required to include these specific conditions in their claims. Recitation of cleavage conditions generally is sufficient. As taught in the original disclosure, the cleavage conditions can be varied, and selected by the user. *See, e.g.,* Col. 39, line 65 through Col. 40, line 18. Within this passage, specific useful cleavage conditions are taught (*see, e.g.,* Col. 40, lines 5-7), as are specific ingredients and parameters that can be varied. For any particular set of cleavage

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[7/] Prior to the instant Amendment, these conditions were referred to as "hybridization conditions" to track the language of the rejection. Applicant believes that using this nomenclature may have unduly confused the situation. For clarity, in this Amendment, Applicant refers to conditions previously referenced as "hybridization conditions" using the more accurate nomenclature "cleavage conditions."

conditions, skilled artisans can readily design 5'- and 3'-polynucleotide probes capable of specifically hybridizing to their respective regions of the predetermined target nucleic acid sequence. Skilled artisans routinely engage in this type of activity. For example, in the context of SNP detection and/or analysis, skilled artisan routinely design oligonucleotide probes that can specifically hybridize to the target under specified assay conditions. In the context of nucleic acid sequencing and/or amplification reactions, skilled artisans routinely design primers that can specifically hybridize to the target under the conditions of the sequencing and/or amplification reaction. Conversely, given specified probe and target sequences, skilled artisans routinely engage in determining conditions suitable for observing specific hybridization.

In sum, the situation is as follows. The original disclosure teaches specific conditions under which FEN-1 polypeptides cleave 5',3'-double flap structures. It is within the routine skill in the art to engage in the design of probes that can specifically hybridize to a predetermined target sequence under the specified conditions. Conversely, the original disclosure teaches that specific conditions for carrying out cleavage by FEN-1 polypeptides may be selected by the practitioner, and provides guidance regarding which ingredients and/or parameters may be varied. Given specified probe and target sequences, it is within the routine skill in the art to be able to select conditions suitable for FEN-1 polypeptide cleavage, and therefore conditions that are suitable for carrying out the methods of amended Claims 21-35. Accordingly, the guidance provided in the original disclosure, coupled with the routine knowledge and skill in the art, fully enables amended Claims 21-35.

B. Kit Claims 59-73 Are Fully Enabled

Amended Claims 59-73 are directed to kits for use in detecting the presence or absence of a predetermined target nucleic acid sequence. The kit comprises a FEN-1 polypeptide and two polynucleotides probes: a 5'-probe and a 3'-probe. As amended, the sequences of these probes are defined by their ability to specifically hybridize to specified portions of the target sequence under FEN-1 polypeptide cleavage conditions. Accordingly, amended Claims 59-73 are fully enabled for the same reasons discussed above in connection with amended Claims 21-35.

C. Hybridization Complex Claims 51-58 Are Fully Enabled

Claims 51-58 are directed to a hybridization complex between three polynucleotides. The hybridization complex is defined by virtue of its ability to adopt or form a 5',3'-double flap structure that is cleaved by a FEN-1 polypeptide. As taught throughout the original disclosure, cleavage of such structures by FEN-1 polypeptides is independent of the particular sequences of the polynucleotides comprising the complex. As a consequence, Applicant need only enable the double-flap structure. Having described the double-flap structure, Applicant has enabled the skilled artisan to readily determine the sequences of 3'- and 5'-probes, as well as the hybridization conditions, suitable to form a double-flap structure given any particular target sequence. As a consequence, Claims 51-58 satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1.

D. Claims 21-35 and 51-73 Are Fully Enabled

For the reasons stated above, Applicant submits amended Claims 21-35 and 51-73 are fully enabled by the original disclosure. Armed with the original disclosure and the knowledge generally available in the art at the time the original application was filed, ordinarily skilled artisans would have had no difficulty practicing the full scope of the various inventions recited in amended Claims 21-35 and 51-73.[8/] Accordingly, Applicant requests that the rejection of Claims 7-73 under the enablement clause of 35 U.S.C. § 112, ¶ 1 be withdrawn.

V. Rejection Under 35 U.S.C. § 112, ¶ 2

Claim 7 stands rejected under 35 U.S.C. § 112, ¶ 2 as being incomplete for allegedly omitting "essential elements." Although Applicant disagrees with the propriety of the rejection for reasons already of record, in order to reduce the issues going forward and to expedite allowance of claims, Applicant has nonetheless cancelled Claim 7, rendering the rejection moot.

[8/] Applicant notes that Claims 7-73 as originally presented in the Preliminary Amendment are likewise fully enabled by the original disclosure.

VI. Conclusion

For the reasons stated above, Claims 21-35 and 51-73 are believed to be in condition for allowance. An early indication of the same is therefore kindly requested. No fees beyond those being submitted concurrently with this Amendment are believed due. However, the Commissioner is authorized to charge any required fees, or credit any overpayment to Deposit Account No. 50-2319.

Respectfully submitted,

Date: August 13, 2003 By: _____

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FULL TEXT OF CASES (USPQ FIRST SERIES)
In re Herschler, 200 USPQ 711 (CCPA 1979)

In re Herschler

(CCPA)
200 USPQ 711

Decided Feb. 1, 1979
No. 78-548
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Affidavits -- In general (§ 12.1)

Patent and Trademark Office's physical possession of original affidavit at time of Board of Appeals' decision makes further verification unnecessary.

2. Applicants for patent -- In general (§ 14.1)

Pleading and practice in Patent Office -- Rules effect (§ 54.9)

Inventorship of great-grandparent application was not effectively amended by Patent and Trademark Office's acquiescence in accepting sole inventorship of grandparent, nor was great-grandparent amended nunc pro tunc by submission of copies of Rule 45 papers.

3. Specification -- In general (§ 62.1)

Specification -- Claims as disclosure (§ 62.3)

Specification -- Sufficiency of disclosure (§ 62.7)

Function of description requirement is to ensure that inventor had possession, as of filing date of application relied upon, of specific subject matter later claimed by him; how specification accomplishes this is not material; claimed subject matter need not be described in haec verba to satisfy description requirement; it is not necessary that application describe claim limitations exactly, but only so clearly that one having ordinary skill in pertinent art would recognize from disclosure that applicant invented processes including those limitations.

4. Specification -- Sufficiency of disclosure (§ 62.7)

Written description of class of compounds must provide measure of predictability for utility described for that class.

5. Pleading and practice in Patent Office -- Rejections (§ 54.7)

It is incumbent, in first instance, for Patent and Trademark Office to give reasons why written description is insufficient.

6. Specification -- Sufficiency of disclosure (§ 62.7)

Known steroids, when considered as class of compounds carried through layer of skin by DMSO, is not so large that single example in specification could not describe varied members with their further varied properties.

7. Specification -- Sufficiency of disclosure (§ 62.7)

Court of Customs and Patent Appeals maintains line first clearly drawn in In re Fuetterer, 138 USPQ 217, where it found written description requirement to be satisfied where claims were drawn to rubber stock composition useful in producing tire treads, included recitation of inorganic salt capable of maintaining homogeneous distribution of another component in composition, and disclosure listed function described and four members of class having that function.

8. Claims -- Specification must support (§ 20.85)

Specification -- Sufficiency of disclosure closure (§ 62.7)

Principles stated in In re Driscoll, 195 USPQ 434, In re Ruschig, 154 USPQ 118, and In re Fried, 136 USPQ 429, concerning application with claims either to intermediate classes of new compounds per se or claims drawn to processes using those new compounds are still alive and well.

9. Specification -- Sufficiency of disclosure (§ 62.7)

Claims drawn to use of known chemical compounds in manner auxiliary to invention must have corresponding written description only so specific as to lead one having ordinary skill in art to that class of compounds; occasionally functional recitation of those known compounds in specification may be sufficient as that description.

10. Patentability -- Evidence of -- State of art (§ 51.467)

Papers presented to New York Academy of Sciences could, where there is prima facie showing of obviousness to rebut, if properly presented, indicate wide-scale acceptance in art and provide secondary consideration capable of overcoming 35 U.S.C. 103 rejection.

Particular patents -- Tissue Penetration

Herschler, Enhancing Tissue Penetration of Physiologically Active Steroidal Agents with DMSO, rejection of claims 1-5 and 9-13 reversed.

Case History and Disposition:

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Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of Robert J. Herschler, Serial No. 304,283, filed Nov. 6, 1972, division of application, Serial No. 69,155, filed Sept. 2, 1970, continuation-in-part of application, Serial No. 753,231, filed Aug. 16, 1968, continuation-in-part of application, Serial No. 329,151, filed Dec. 9, 1963. From decision rejecting claims 1-5 and 9-13, applicant appeals. Reversed.

Attorneys:
Stanley M. Teigland, San Francisco, Calif., for appellant.

Joseph F. Nakamura (Fred W. Sherling and Ernest G. Therkorn, of counsel) for Commissioner of Patents and Trademarks.

Judge:
Before Rich, Baldwin, and Miller, Associate Judges, and Kashiwa, [*] and Ford, [**] Judges.

Opinion Text

Opinion By:
Baldwin, Judge.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) affirming the rejection of claims 1-5 and 9-13 in appellant's application serial No. 304,283, [1] filed November 6, 1972, for "Enhancing Tissue Penetration of Physiologically Active Steroidal Agents with DMSO." [2]

The board affirmed the examiner's rejection of all claims under 35 USC 103 as unpatentable over Lubowe in view of Faust, Marson or Brown. The board also affirmed a rejection, first entered pursuant to its authority under 37 CFR 1.196(b), [3] of each of the claims under 35 USC 102(b) or 103 over Stroughton et al., Stroughton or Kligman. [4] We reverse.

The Invention

The appellant has found that DMSO enhances the penetration of a number of materials through skin tissue. In the application at hand, a mixture of DMSO and a "physiologically active steroidal agent" is administered to skin (or a mucous membrane) with the result that the steroid penetrates the membrane. The claimed process provides such advantages as the elimination of injection by needle and the ability to administer localized doses of the drug without resort to a systemic dose.

Claim 1 is typical of the invention:

> 1. A method of enhancing the penetration into and across an external membrane barrier of a human or animal subject of a physiologically active steroidal agent capable of eliciting a physiological effect upon topical application thereof, which comprises the concurrent topical administration to the external membrane of an amount of said steroidal agent effective to produce the desired physiological effect and an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect.

The Prior Art

The following references were relied upon to support the rejection under §103:

> Lubowe Patent No. 2,942,008 issued on June 21, 1960.
>
> Brown et al., "A Note on the Toxicity and Solvent Properties of Dimethyl Sulfoxide,"

> 15 J. Pharm. Pharma. Col. 688-692 (Oct. 1963).
>
> Faust, "Some New Components for Cosmetic and Dermatologic Vehicles," 77 American Perfumer 23-26 (Jan. 1962).
>
> Marson, "Il Dimetilsolfossido Solvente Aquo-Mimetico," 102 Boll. Chimicofarm. 109-124 (Feb. 1963).

Lubowe is a patent directed to compositions with large amounts of mineral, vegetable or animal oils solubilized in short chain alcohols. The oils are maintained in solution by the addition of fatty alcohols having 10 to 24 carbon atoms. The resulting compositions may be used as a base in a number of further cosmetic and pharmaceutical compositions. When the composition is used in a hair lotion, Lubowe indicates that "estrogenic hormones, methyl sulfoxide" may be added. Example XII shows a hair lotion containing 0.1% estrogenic hormone in 50% ethyl alcohol but without DMSO.

Brown et al. shows DMSO to be a solvent in which many classes of compounds are soluble and, further, is of low toxicity.

Faust suggests that DMSO is a "safe and effective solubilizing" agent suitable for use as a cosmetic or dermatologic vehicle.

Marson cites Faust saying "the cosmetic literature has recently cited its [DMSO's] employment as simple, non-gelated components of dermatological vehicles" and describes the usefulness of DMSO in preparing pharmaceutical compositions containing, inter alia, the thickening agents such as recited in the claims.

Background

The examiner indicated in the Final Rejection and in his Answer that the claims were rejected under 35 USC 103 since "the Lubowe patent describes, inter alia, DMSO added to Ex. XII, an anti-seborrheic hair lotion containing 1/10 part by weight of estrogenic hormone," and that, "we have, inherently, the same process involved here as described in Lubowe, notwithstanding applicant's observation of percutaneous absorption from the DMSO (apparently added as a vehicle or solvent, according to Faust, Marson or Brown)."

The board, in a first opinion, agreed with the Examiner's position and amplified it, stating:

> We note that the secondary references make it clear that DMSO is an effective solubilizing agent for various drugs, including those to be applied topically and along with the examiner we emphasize that ". . . an amount of DMSO sufficient to effectively enhance penetration . . ." of the steroid is also an amount effective for solubilization of the steroid; compare with page 19 of the specification. Therefore, we find that it would be obvious to add DMSO to the steroid containing formulation of Example XII of Lubowe in amounts large enough to enhance penetration of said steroid, in view of the teachings of the secondary references regarding DMSO's utility as a solvent for topical drug formulations.
>
> The board made an additional rejection:
>
> Under the provisions of 37 CFR 1.196(b) we make new grounds of rejection under 35 USC 102(b) and 35 USC 103 against claims 1 to 5 and 9 to 13.
>
> Claims 1 to 5 and 9 to 13 are rejected under 35 USC 102 and 35 USC 103 as unpatentable over any one of Stoughton et al, Stoughton or Kligman. All of the above publications were made of record by appellant's counsel in Paper No. 6 of great-grandparent case Serial No. 329,151 filed December 9, 1963. The above articles were described in detail by appellant's counsel in said Paper No. 6 (pages 8 to 12) and we will not, therefore, elaborate on the disclosure of the articles. It is sufficient to note that each of the articles teaches the enhanced penetration of various steroids resulting from topical application of DMSO concurrently with the steroid -- the heart of appellant's inventive concept. All of the above articles were published in 1964 or 1965, more than one year prior to the filing date of appellant's grandparent case Serial No. 753,231, filed August 16, 1968. Hence the articles are statutory bars against the present claims under 35 USC 102(b) and 103 *unless* appellant's claimed invention was described in great-grandparent case Serial No. 329,151 filed December 9, 1963; see 35 USC 120 and 35 USC 112, first paragraph.

> We have carefully considered the great-grandparent case but the only disclosure relating to steroids (pages 34-35) is limited to glucocorticosteroids whereas *all* of the present claims on appeal are drawn either to steroids in general or to steroids not limited to glucocor-ticosteroids (claims 4-5). It is now well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim; In re Ruscetta et al, 45 CCPA 968, 255 F.2d

> 687, 118 USPQ 101 (1958), In re Lukach, 58 CCPA 1233, 442 F.2d 967, 169 USPQ 795 (1971) and In re Smith, 59 CCPA 1025, 458 F.2d 1389, 173 USPQ 679 (1972).
>
> Hence, appellant may not rely upon his great-grandparent case to support any of the claims on appeal and thus the above articles are prior art and can be properly applied against the claims under 35 USC 102(b) and 103. We note also that the great-grandparent case was filed in the name of Jacob and Herschler, whereas the present case was filed by Herschler alone. Since the inventive entities are different, we do not see how appellant can claim priority under 35 USC 120 based upon the great-grandparent case; note the requirement that the applications be ". . . filed by the same inventor . . . ." [Emphasis in original.]

Appellant thereupon submitted a Request for Reconsideration accompanied by two attachments and requested that the examiner consider them. The first attachment was a portion of a 508 page collection of papers given at a conference entitled Conference on Biological Actions of Dimethyl Sulfoxide held by the New York Academy of Sciences in 1974. The second enclosure was a copy of a Rule 45 declaration [5] submitted in the great-grandparent application purporting to amend the inventorship from Jacob and Herschler joint to Herschler sole.

In support of the Rule 45 affidavit, appellant argued:

> With respect to the first reason, submitted herewith are copies of papers filed under Rule 45 in the great-grandparent application, and a copy of a postcard receipt indicating that the papers were received by the Patent Office. The papers include an amendment under Rule 45 to change the inventorship of the great-grandparent application to correspond to the inventorship of this application. No notice was received that entry of the amendment was refused. Moreover, the Rule 45 papers were filed simultaneously with a continuing application in the name of the new inventorship and the Patent Office accorded continuation-in-part status to the application, which issued as U.S.P. 3,551,554. Hence, it is evident that the examiner considered the papers filed under Rule 45 and acknowledged that they were legally sufficient to change the inventorship. However, if the examiner believes it is necessary to formally change the inventorship of the great-grandparent application, he is invited to enter the Rule 45 amendment nunc pro tunc.

Appellant further argued that the written description in the great-grandparent was adequate for the subgenus now claimed:

> As clearly indicated in the great-grandparent application, appellant recognized from the start that the invention was applicable to physiologically active agents in general. * * * Thus, the Board's contention that "the only disclosure [in the great-grandparent application] relating to steroids is limited to glucocorticosteroids" is incorrect. The great-grandparent application discloses that the invention is applicable to the genus of physiologically active agents, which includes the important subgenus of steroids. A working example illustrates practice of the invention with a corticosteroid, which, of course, is a species of the subgenus of steroids. Hence, the great-grandparent application, in teaching the applicability of the invention to the genus of physiologically active agents in general, and to the species corticosteroids in particular, quite naturally describes to one skilled in the art the applicability of the invention to the subgenus of steroids. Since a corticosteroid is obviously a type of steroid, and since the word "corticosteroid" contains the very word "steroid", the corticosteroid in the working example, in view of the applicability of the invention to physiologically active agents in general, clearly represents to one skilled in the art the subgenus of steroids. There is no other subgenus that it would reasonably represent.

The collection of papers submitted to the New York Academy of Sciences was said to demonstrate that "in view of the interest in DMSO generated by appellant's discovery, as shown by this reference, the discovery was truly a pioneering breakthrough in medical science." And further, that the papers describing work by:

> Kligman and others with just a few different species of steroids [show], that DMSO enhances the penetration of steroids in general. This same conclusion would similarly be drawn by one skilled in the art from the disclosure in appellant's great-grandparent application. Thus, the great-grandparent application describes to one skilled in the art the invention claimed in this application.

The board remanded the application to the examiner for consideration of the appended paper. In a supplemental Answer, the examiner stated:

> The Examiner respectfully declines the invitation to either now enter, nunc pro tunc, in an abandoned application, or to even consider what precisely Stanley Jacob did, or not, co-invent, in unverified copies of submitted purported Rule 45 amendment papers, which papers, even if not untimely, are unclear: ("various embodiments", "several additional embodiments", "I was informed on July 18, 1968 that I was not a coinventor", etc.), and considers them not relevant or sufficiently precise to any specific issues herein of whether or not he did not in fact co-invent the applicable portions of S.N.329,151, filed jointly with him, which relate to DMSO topically applied with a species of glucocorticosteroid * * *. [Furthermore, the board expressly states that] "we have carefully considered.", but they found, (and appellant has not denied,) that its only disclosure relating to steroids (pages 34-35) is limited to the single species of glucocorticosteroids, whereas *all* of the present claims on appeal are drawn either to steroids in general, or to steroids not limited to glucocorticosteroids (claims 4-5), and the Board of Appeal [sic] held it to be now well settled law that disclosure of a species is insufficient to provide descriptive support for a generic or sub-generic claim, citing the Ruscetta et al, Lukach and Smith decisions. Assuming, arguendo, that the precise inventorship of said glucocorticosteroid species and DMSO is established as not involving a different inventorship question; the question remains, for review under 35 USC 141 or 145, where, in S.N. 329,151, is described the steroid genus or subgenus, now claimed? [Emphasis in original.]

The application was then returned to the board. Appellant filed another request for reconsideration reiterating the comments and arguments made in the earlier request.

> The board's final opinion indicated that:
>
> We agree with the Examiner that the unverified and unclear papers purportedly filed under 37 CFR 1.45 do not establish that the inventorship of 329,151 and that of the instant case are the same.
>
> We have carefully reconsidered our new ground of rejection under 35 USC 102(b) and 103 over the newly cited art but we are convinced that the rejection is sound. Apart from the different inventive entities of 329,151 and the instant case we remain of the view that there is no description [in] 329,151 of the process as applicable to steroids. In In re Smith, 178 USPQ 620 (1973), there was also a description in the parent case of a broad genus and a particular species, yet the CCPA held that there was insufficient descriptive support for a subgeneric claim similar to the present subgenus claims drawn to steroids. We do not see how an article published in 1974 or 1975 can aid appellant in overcoming the deficiencies in disclosure of an application filed December 9, 1963. The fact remains that nowhere in Serial No. 329,151 is there any mention of the term "steroids," let alone a description of the claimed process as applicable to steroids as a class.

We reiterate our position that claims 1 to 5 and 9 to 13 are obvious over Lubowe in view of any one of Faust, Marson or Brown under 35 USC 103. We do not agree with appellant that it would not be obvious to solubilize steroids (such as the estrogenic hormone in Example XII of Lubowe) with DMSO. As explained by the Examiner in his answer, the secondary references make it clear that DMSO is an effective solubilizing agent for various drugs, including those to be applied topically. We emphasize again that ". . .an amount of DMSO sufficient to effectively enhance penetration . . ." of the steroid is also an amount effective for solubilization of the steroid. We therefore find clear motivation from the teachings of the prior art to solubilize steroids intended for topical application by adding DMSO to steroid formulations in an

amount sufficient to solubilize components of the steroid formulation. The fact that appellant may use DMSO for a different purpose (as compared to the prior art teachings that DMSO solubilizes drugs to be applied topically) does not alter the conclusion that its concomitant use with topically applied drugs such as estrogen would be prima facie obvious from the purpose disclosed in the references; In re Lintner, 173 USPQ 560, 562 (CCPA 1972).

Opinion

35 USC 102(b)/103 Rejection over Stroughton et al., Stroughton or Kligman

As noted above, appellant concedes that the substance of this rejection is proper if the court finds either the great-grandparent application lacks a written description of the instant invention [6] or the inventorship of the great-grandparent application differs from the one on appeal. The analysis need only consider those two points.

Rule 45 Affidavit

[1]The board found that the "unverified [7] and unclear papers * * * do not establish that the inventorship of 329,151 and that of the instant case are the same." We do not agree.

Jacob's affidavit indicated that he learned of the invention from the appellant:

> Herschler disclosed at this meeting his conception of the invention of enhancing tissue penetration of physiologically active agents by applying them to animal tissue (both topically and internally) together with DMSO and his reduction to practice of various embodiments of this invention. Herschler requested at this meeting that my group test various additional embodiments of this invention for him.

and that his participation "concerning the invention disclosed and claimed in application Serial No. 329,151 was limited to assisting in further testing of the invention with such additional pharmacologically active agents."

Although the affidavit is somewhat vague regarding specific acts done by the affiant, it is quite clear that he derived all information pertinent to the disclosed invention from Herschler and acted only under Herschler's direction. The affidavit is consistent with a finding that Jacob was not an inventor in the great-grandparent application. The accompanying affidavit of Herschler (ratifying the statement of Jacob), in conjunction with the originally filed application papers, leads us to the conclusion that Herschler believes himself to be the inventor of the matter disclosed and claimed in the great-grandparent application.

[2]This is not to say that we agree with appellant that the inventorship of the great-grandparent application was effectively amended by the PTO's acquiescence in accepting the sole inventorship of the grandparent nor do we agree that the great-grandparent was amended nunc pro tunc by the submission of copies of the Rule 45 papers. We consider the affidavits sufficient, for the purpose of claiming priority under § 120, to demonstrate that Jacob was joined as a coinventor through error without deceptive intent. Weil v. Fritz, 572 F.2d 856, 196 USPQ 600 (CCPA 1978); In re Schmidt, 48 CCPA 1140, 293 F.2d 274, 130 USPQ 404 (1961).

Written Description in the Great-Grandparent

The appealed claims recite a subgenus, i.e., physiologically active steroidal agents, not found in haec verba in the great-grandparent application.

Appellant emphasizes the following quotation found in the great-grandparent specification and argues that it clearly defines a genus to which the subgenus of steroids belongs:

> By the term "physiologically active substance" is meant any substance which has a demonstrable and desired physiological activity in the sense that animal tissue responds thereto. This may be an altered physiologic phenomenon following heparin administration; a pharmacological activity such as local anesthesia; an antibacterial activity following administration of antibiotics; a bacteriostatic activity following the administration of iodine; a growth stimulation

> activity following usual access to dietary sources, and the like. The term is intended to include any desirable pharmacological action with compounds alien to animal tissue, and any physiological activity with compounds normally occurring in animal tissue. It is also meant to include within the term "physiologically active substance" materials which are diagnostic tools such as radiopaque agents (for instance, iodine), dyes and the like.

That application exemplifies a single species within the terms of claim 1 of this appeal:

Example 30

Penetration of Corticosteroids

> A twenty-four year old medical student was seen with atopic dermatitis of the right antecubital fossa. Three cc. of 100% dimethyl sulfoxide were applied four times daily for three days. No benefit was noted. One mg. or 1/4 cc. of Decadron (dexamethasone 21-phosphate) was applied four times a day for two days without benefit. One mg. of dexamethasone 21-phosphate in 3 cc. of 100% dimethyl sulfoxide was painted onto the involved area four times daily for three days. At the end of this period all evidence of the inflammatory reaction had disappeared.
>
> This example shows an improved action of dexamethasone 21-phosphate when used with dimethyl sulfoxide.

No other language in that specification specifically discusses topical application of a steroid-containing composition.

However, the remaining examples are awesome in their diversity. The scope of exemplified "physiologically active substances" includes iodine (Example 1), pressed pellet feed for rats (Example 4), penicillin (Example 10), procaine (Example 16), various chemotherapeutic agents (Examples 17 & 18), barbiturates (Example 19), oral insulin (Example 21), antihistamines (Example 29), various local anesthetics (Examples 34 & 35), etc.

[3]The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied upon, the specific subject matter later claimed by him; how the specification accomplishes this is not material. In re Smith, 481 F.2d 910, 178 USPQ 620 (CCPA 1973). The claimed subject matter need not be described in haec verba to satisfy the description requirement. In re Smith, 59 CCPA 1025, 458 F.2d 1389, 173 USPQ 679 (1972). It is not necessary that the application describe the claim limitations exactly, but only so clearly that one having ordinary skill in the pertinent art would recognize from the disclosure that appellants invented processes including those limitations. In re Smythe, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973).

The question is simple: does the array of information supplied by appellant in the great-grandparent application teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process. We conclude that it does.

[4][5][6]A toehold on the problem is found in In re Cook, 58 CCPA 1049, 439 F.2d 730, 169 USPQ 298 (1971). The written description of a class of compounds must provide a measure of predictability for the utility described for that class. That is to say: would the worker of ordinary skill in this art consider "steroidal agents" to be operative when considering the great-grandparent's disclosure? It is incumbent, in the first instance, for the PTO to give reasons why he would not. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 98 (CCPA 1976). The solicitor urges that the class of steroids is so large that a single example in the specification could not describe the varied members with their further varied properties. We disagree with this contention. Steroids, when considered as drugs, have a broad scope of physiological activity. On the other hand, steroids, when considered as a class of compounds carried through a layer of skin by DMSO, appear on this record to be chemically quite similar. The diversity of exemplified materials "potentiated" by DMSO in the great-grandparent application, is *much broader* than the diversity of steroid compounds shown contemporaneously in the art. [8]In this instance, we conclude that one having ordinary skill in this art would have found the use of the subgenus of steroids to be apparent in the written description of the great-grandparent application.

Were this application drawn to novel "steroidal agents," a different question would be posed.

[7]We wish to maintain the line first clearly drawn in In re Fuetterer, 50 CCPA 1453, 319 F.2d 259, 138 USPQ 217 (1963).

There, claims drawn to a rubber stock composition useful in producing tire treads included a recitation of "an inorganic salt capable" of maintaining an homogeneous distribution of another component in the composition. The disclosure listed the function desired and four members of the class having that function. This court found the written description requirement to be satisfied:

> Appellant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure.
>
> We are not persuaded that our conclusion on this point is wrong by decisions of this and other courts relating to the sufficiency of invention disclosures in cases wherein the applicant is claiming chemical *compounds* per se. [Emphasis in original.]

[8]Id. at 1462, 319 F.2d at 265-266, 138 USPQ at 223. Applications with claims either to intermediate classes of *new compounds* per se or claims drawn to processes *using* those *new compounds* have been considered by this court on other occasions. In re Driscoll, 562 F.2d 1245, 195 USPQ 434 (CCPA 1977); In re Ruschig, 54 CCPA 1551, 379 F.2d 990, 154 USPQ 118 (1967); In re Fried, 50 CCPA 954, 312 F.2d 930, 136 USPQ 429 (1963). The principles stated therein are still alive and well.

[9]In sum, claims drawn to the *use* of *known* chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description. In Fuetterer and here, such is the case.

35 USC 103 Rejection over Lubowe in view of Faust, Marson or Brown

Throughout the Lubowe patent, DMSO is mentioned only once, and that occurs in the statement that DMSO, as well as many other enumerated compounds, may be added to hair lotion preparations containing a solubilized oil. There is no indication of why the DMSO would be added; nor is there any teaching that there is any relationship between DMSO and estrogenic hormones (which are steroids), let alone a suggestion to employ them in combination. The board relies upon the secondary references to show "that DMSO is an effective solubilizing agent for various drugs, including those to be applied topically" and accordingly finds it obvious to utilize DMSO in Lubowe's Example XII. Such a conclusion is not supported by the record, because, as appellant notes, "the formulation of [Lubowe's] Example XII is already a clear solution containing more solvent than anything else. Moreover, the alcohol solvent employed in Lubowe is also a solvent for steroids." Hence, there would have been no reason for one skilled in the art to add any additional solvent to Lubowe's formulations, particularly a totally different solvent "in any amount large enough to enhance penetration," as required by the claims. Nor would it have been obvious to one skilled in the art to substitute DMSO for a portion of the exemplified alcohols, since Lubowe's invention is directed to the use of specific combinations of alcohols in the disclosed formulations.

While the secondary references may teach that DMSO is generally useful as a solvent, there is no suggestion or teaching in any of them to combine it with a steroid -- that is, to choose DMSO from among the countless number of solvents as the solvent for steroids.

[10]Appellant argues that Brown, by stating that DMSO is "not known to interfere with absorption or metabolism," is a teaching not to use DMSO. The solicitor, on the other hand, characterizes the same quotation by saying that "it is not clear how this teaching is a teaching away * * * [and, accordingly] there should be no suprise [sic] that DMSO enhances penetration." Even though that quotation from Brown cannot be said to be an overwhelming suggestion to use DMSO for any solvent-type utility, we do not see how it provides any motivation for one skilled in the art to use DMSO in the formulation of Lubowe. The references do not provide any impetus to do what appellant has done nor do they provide the

art with the knowledge that DMSO enhances penetration of "steroidal agents" through a membrane. [9]

Summary

We *reverse* the decision of the board, which decision affirmed a rejection of the claims both under 35 USC 102 and 103.

Reversed.

Footnotes

Footnote 1. This application is a division of serial No. 69,155, filed September 2, 1970, now U.S. 3,711,606, which in turn is a continuation-in-part of serial No. 753,231, filed August 16, 1968, now U.S. 3,551,554, which is a continuation-in-part of application serial No. 329,151 (hereafter the "great-grandparent"), filed December 9, 1963, now abandoned.

Footnote 2. Dimethyl sulfoxide (hereinafter DMSO) is a water-clear, water-miscible, hygroscopic, neutral organic liquid, melting at about 18°C. and boiling at about 189°C. It is a well-known industrial solvent represented by the following formula:
Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Footnote 3. 37 CFR 1.196(b) provides, in pertinent part, that:

> (b) Should the Board of Appeals have knowledge of any grounds not involved in the appeal for rejecting any appealed claim, it may include in its decision a statement to that effect with its reasons for so holding, which statement shall constitute a rejection of the claims.

Footnote 4. These references were not part of the certified record transmitted to the court. However, appellant admits in his brief that the rejection is proper *if* the great-grandparent lacks a written description of the invention in issue. The contents of the references need not be considered.

Footnote 5. Rule 45(b) of the Rules of Practice in Patent Cases provided, at the time of the affidavit in issue (1965), that:

> (b) If an application for patent has been made through error and without any deceptive intention by two or more persons as joint inventors when they were not in fact joint inventors, the application may be amended to remove the names of those not inventors upon filing a statement of the facts verified by all of the original applicants, and an oath or declaration as required by rule 65 by the applicant who is the actual inventor, provided the amendment is diligently made. Such amendment must have the written consent of any assignee.

Footnote 6. We assume, in the absence of any argument to the contrary, that the parent and grandparent applications contain the necessary written description of the invention on appeal. See In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).

Footnote 7. It is not altogether clear what is meant by "unverified" in referring to the copy of the affidavit submitted to the examiner. The PTO had physical possession of the original affidavit at the time of the board decision as is evidenced by a certified copy thereof in the transcript submitted to the court. Further verification seems unnecessary.

Footnote 8. See, e.g., Kirk-Othmer, "Sterols and Steroids," 12 Encyclopedia of Chemical Technology 917-947 (1st Ed. 1954).

Footnote 9. We do not find it necessary to reach the question of the weight to be given the papers presented to the New York Academy of Sciences in that appellant has no prima facie showing of obviousness to rebut. Were such a showing appropriate, these papers could, if properly presented, indicate wide-scale acceptance in the art and provide a secondary consideration capable of overcoming a §103 rejection.

Footnote * The Honorable Shiro Kashiwa of the United States Court of Claims, sitting by designation.

Footnote ** The Honorable Morgan Ford of the United States Customs Court, sitting by designation.

- End of Case -

ISSN 1526-8535

FULL TEXT OF CASES (USPQ FIRST SERIES)
In re FUETTERER, 138 USPQ 217 (CCPA 1963)

In re FUETTERER

(CCPA)
138 USPQ 217

Decided June 28, 1963
Appl. No. 6897
U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Claims--Indefinite--In general (§ 20.551)

Specification--Sufficiency of disclosure (§ 62.7)

Rejection of claims as failing to enable public "to determine operable proportions" is misplaced; such is the function of the invention description and not that of claims.

2. Specification--In general (§ 62.1)

Both the invention description and claims form parts of application's specification.

3. Claims--Functional--In general (§ 20.451)

"Functional" language in claims is not expressly condemned by patent statutes; only portion of 35 U.S.C. which makes any reference to use of statements of function is third paragraph of section 112, which specifically authorizes such use; if rejection based on "functionality" is to be affirmed, it must be on basis that (1) type of "functionality" involved is neither comprehended nor authorized by third paragraph of section 112 and (2) there exists a body of extrastatutory case law which specifically condemns type of "functionality" involved in instant claims.

4. Claims--Functional--Defining ingredient, structure or use (§ 20.453)

Claims directed merely to a "desired result" are objectionable primarily because they cover any means which anyone may ever discover of producing the result.

5. Claims--Functional--Defining ingredient, structure or use (§ 20.453)

Claim is allowed although applicant's inorganic salt is defined in terms of what it does rather than what it is, since a limited use of terms of result to define an essential quality of applicant's salt to one skilled in the art is permissible.

6. Claims -- Functional -- In general (§ 20.451)

Third paragraph of 35 U.S.C. 112 is not necessarily in derogation of previous case law and, therefore, need not be strictly construed.

7. Claims -- Functional -- In general (§ 20.451)

Last paragraph of 35 U.S.C. 112 is not limited to claimed combination involving mechanical structures or apparatus and methods; "combination" in this paragraph includes not only a combination of mechanical elements but also a combination of substances in a composition claim or steps in a process claim.

8. Claims--Broad or narrow--Chemical (§ 20.203)

Specification--Sufficiency of disclosure (§ 62.7)

Claims are not rejected for undue breadth on the ground that an undue amount of experimentation is necessary to determine suitability of undisclosed salts to operate in applicant's claimed combination, since applicant's invention is the combination claimed and not the discovery that certain inorganic salts have specific properties; patent law does not require applicant to discover which of all those salts have such properties and which will function properly in his combination; his invention description indicates that any inorganic salt which has such properties is usable in his combination; if others in the future discover what inorganic salts additional to those enumerated do have such properties, applicant will have no control over them per se; claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by applicant in his disclosure.

Particular patents--Tire Treads

Fuetterer, Tire Treads and Rubber Stock Therefor, claims 38 to 49 of application allowed.

Case History and Disposition:

Appeal from Board of Appeals of the Patent Office.

Application for patent of Charles T. Fuetterer, Serial No. 498,089; Patent Office Division 50. From decision rejecting claims 38 to 49, applicant appeals. Reversed; Worley, Chief Judge, with which Almond, Judge, joins, dissenting with opinion.

Attorneys:
JOHN MAHONEY, Cleveland, Ohio (J. HAROLD KILCOYNE, Washington, D.C., of counsel) for appellant.

CLARENCE W. MOORE (JACK E. ARMORE of counsel) for Commissioner of Patents.

Judge:
Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

Opinion Text

Opinion By:
RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the rejection of claims 38-49 in application Ser. No. 498,089, entitled "Tire Treads and Rubber Stock Therefor." The claims stand rejected solely as "failing to define the alleged invention properly." More specifically, claims 38, 40, 42, 44, 46, and 48 have been rejected as "indefinite and ambiguous" and all claims as "unduly broad and functional."

Appellant's invention relates to a tread stock usable, for example, in vehicle tire treads which are alleged to "improve the traction of * * * tires when they engage a road or pavement which is wet or which is wholly or partly covered with a water-containing substance, such as snow or ice."

Appellant describes his invention as follows:

> In accordance with the present invention, a carbohydrate, a protein, or
>
> Page 219
>
> mixture thereof, which is insoluble or which is only slightly soluble in cold water but which forms a colloidal suspension therein, together with one or more inorganic salts which are effective in maintaining the carbohydrate, protein, or mixture thereof, in colloidal suspension in the film of water which forms around the tire tread when the tire engages a wet or icy road or pavement, [1] are incorporated in a finely divided state in rubber, together with the other compounding ingredients which have previously been utilized in combination with rubber, to form the rubber stock for forming the tire tread. [2]

Claim 38 is representative and reads as follows:

> 38. A rubber stock for producing tire treads including as the base portion a major proportion of rubber, a sufficient amount of a vulcanizing agent to vulcanize the rubber, and a reinforcing agent in an amount sufficient to provide a tread stock having high abrasive resistance, said rubber stock also including in addition to the base portion a mixture of a nonadhesive protein and a carbohydrate [3] which mixture is substantially insoluble in cold water and which is homogenously [sic] distributed throughout the base portion of the rubber stock, said mixture of carbohydrate and protein being approximately of a particle size that is fine enough to pass through a 300 mesh screen and being present in an effective amount ranging from more than incidental [4] impurities up to 20% by weight of the base portion of the rubber stock, and an inorganic salt that is capable of holding a mixture of said carbohydrate and protein in colloidal suspension in water, said inorganic salt being in a sufficiently finely divided state to form a homogenous [sic] mixture with the base portion of the rubber stock and being homogenously [sic] distributed throughout the base portion of the rubber stock and being present in an effective amount ranging from more than incidental [5] impurities up to 20% by weight of the base portion of the rubber stock and in an amount sufficient to hold the mixture of carbohydrate and protein in colloidal suspension in a film of water which forms around a tire tread composed of the stock when the tread rotatably engages a wet or icy road or pavement and small particles of the base portion of the rubber stock and small particles of the carbohydrate, protein, and the inorganic salt are worn from the tread.

The Definiteness of the Claims

The rejection of claims 38, 40, 42, 44, 46, and 48 as indefinite and ambiguous was set forth by the examiner in his answer as follows:

> The recitation "present in an effective amount ranging from more than incidental impurities," limiting the amount of salt, protein and/or carbohydrate present is indefinite and ambiguous since it is neither apparent how much constitutes an effective amount nor is it obvious what constitutes an incidental impurity.

The board, while ostensibly affirming this rejection, noted that the portion of the claims quoted by the examiner did not make the tire tread stock recited therein distinguishable from that disclosed by

Davis et al., [6] a reference considered by the examiner to be inapposite to the claims now before us.

After considering the Davis et al. disclosure in detail, we are unable to see its pertinence to the claims in their present form. This conclusion finds support in the failure of the solicitor to do more than note the existence of the Davis et al. reference and mention in a cursory fashion the manner in which the board made use of it in "affirming" the examiner.

The essence of the Patent Office rejection on indefiniteness is that a recitation in the *claims* of "an effective amount ranging from more than incidental impurities" would place an "undue burden * * * upon the public, to determine the operable proportions."

[1] We think the examiner's rejection of the instant claims as failing to *enable* the public "to determine operable proportions" is misplaced. Such is the function of the *invention description* and not that of the claims. [7] Appellant stated before the board that when "any amount of the non-adhesive protein, carbohydrate, or a mixture thereof, is present, some effect will be obtained." The Patent Office does not dispute this statement. As in the case of In re Gay, 50 CCPA 725, 309 F.2d 769, 135 USPQ 311, when we consider what appellant's invention really is, we find that appellant has clearly stated *in the written description of his invention* that a particular aspect thereof is not crucial, in this instance that one could vary within wide limits the amounts of non-adhesive protein and/or carbohydrate and still achieve an operable form of his invention. We do not consider pertinent to the instant rejection, which is not based on prior art, the obvious fact that if extremely small quantities of carbohydrate and/or nonadhesive protein were used the "effect * * * obtained" would be extremely small. Accordingly, insofar as the instant rejection on indefiniteness and ambiguity may be considered to be based on the failure of appellant to comply with the requirements of the *first* paragraph of 35 U.S.C. 112, we are not persuaded that any "undue burden" is placed on the public by appellant's disclosure. We therefore reverse the rejection of claims 38, 40, 42, 44, 46, and 48 as indefinite and ambiguous.

The Undue Breadth and Functionality of the Claims

This rejection was set forth by the examiner in his answer as follows (emphasis ours):

> The recitation "inorganic salt that is capable of holding a mixture of said protein and/or carbohydrate in colloidal suspension" is unduly broad and functional. "Inorganic salt" reads on literally thousands of materials, many of which would *not be operative* for applicant's purpose. For example, some salts *could* readily react with the other ingredients in the composition while other salts *could* be corrosive or destructive of the rubber. This recitation is functional since it merely describes how the salt functions as the surface of the tire wears away. It is well established that claims should set out what the materials are and not by what they do. In re Fullam, 1947 C.D. 352 [34 CCPA 1018, 161 F.2d 247, 73 USPQ 399].

The board affirmed this portion of the examiner's rejection, stating:

> While the examiner has not specifically listed any salt as being inoperative, his rejection is not based upon the ground of inoperativeness per se but rather upon the inordinate breadth of

> the claimed salts when it is not apparent from the disclosure of only four salts what other salts would be suitable to serve the function asserted and required by the claims.

(a) Functionality

[3] "Functional" language in claims is not expressly condemned by the patent statutes. On the contrary, the only portion of Title 35, U.S.C., which makes any reference to the use of statements of function specifically authorizes such use. [8] If we are to affirm the Patent Office rejection based on "functionality," therefore, we must do so on the basis that (1) the type of "functionality" involved here is neither comprehended nor authorized by the third paragraph of 35 U.S.C. 112 *and* (2) there exists a body of extrastatutory case law which specifically condemns the type of "functionality" involved in the instant claims. [9]

The board stated, as previously noted, that "Since the alleged novelty appears to reside in the result desired to be obtained by the salts, it is not proper to define the salt by what it is supposed to do rather than what it does." [10]

The sole cited support for the board's position was the Fullam case, supra, a 1947 decision of this court which we feel involved a phase of the "functionality" question which is inapposite to the instant case.

[4] In the Fullam case, this court stated that some claims were properly rejected as "functional in claiming merely the desired result well known to and sought after by workers skilled in the art." Claims directed *merely* to a "desired result" have long been considered objectionable primarily because they cover any means which anyone may ever discover of producing the result. See, e.g., O'Reilly v. Morse, 15 How. 62; Heidbrink v. McKesson, 290 F. 665.

The desired result of appellant's invention is limiting the skidding of a tire tread stock on a wet surface. Appellant, in the claims before us, is not claiming this result. A myriad of alternative means for achieving this result can be easily thought of which would not require the particular combination of substances claimed by appellant. Insofar, therefore, as a "functional" claim may mean one which covers all means of arriving at the desired result, although the means by which such result is obtained is entirely different from that disclosed by the applicant, it is apparent that appellant's claims are not "functional."

This court in the Fullam case affirmed the rejection of certain other method claims on the basis that a polishing material recited therein was defined "not in terms of *what it is,* but of what it does. [Emphasis ours.]" This court cited General Electric Co. v. Wabash Appliance Corp. et al., 304 U.S. 364, 37 USPQ 466 , to support this proposition.

It was in the Wabash case that the Supreme Court condemned the use of "conveniently functional language at the exact point of novelty." The "exact point of novelty" in the Wabash case resided in statements in the claims which "distinguished [the large grained tungsten filament there involved] from the old art solely by its tendency to remedy the problems in the art met by the patent." Aside from such statements, the Supreme Court specifically held that the claims "aptly * * * describe the product of earlier manufacture."

In the instant case appellant's "exact point of novelty" is a *new combination* of substances constituting a rubber tire tread stock. This combination is distinguishable "from the old art" in that, inter alia, it is new, i.e., no evidence exists that it describes a "product of earlier manufacture." The tendency of appellant's combination to remedy the

tire skidding problems in the art is not even mentioned in the appealed claims.

[5] It is true that appellant's inorganic salt *is* defined in terms of "what it does" rather than "what it is." We note, however, that the Supreme Court, in a seldom quoted passage in the Wabash case, stated, 37 USPQ at 469:

> A limited use of terms of effect or result, which accurately define the essential qualities of a product to one skilled in the art, may in some instances be permissible and even desirable * * *.

Appellant in the instant case has made just such a use of terms of result to define an essential quality of his inorganic salts.

[6] Having carefully reconsidered the Wabash case and others, we are unable to agree with the Patent Office Solicitor that the third paragraph of 35 U.S.C. 112 is necessarily "in derogation of the previous case law" and therefore "must be strictly construed." [11]

[7] Furthermore, we are also unable to agree with the solicitor when he states that "the last paragraph of 35 U.S.C. 112 is by its very language limited to claimed combinations involving mechanical structures or apparatus and methods." The word "combination" in this paragraph includes "not only a combination of mechanical elements, but also a combination of substances in a composition claim, or steps in a process claim." P. J. Federico, Commentary on the New Patent Act, 35 U.S.C.A. Vol. 1, p. 25 (1954). We agree with that statement in the commentary, which is fully supported by the legislative history.

We find particularly appropriate at this point the following words of an eight-man Patent Office Board of Appeals in Ex parte Ball and Hair, 99 USPQ 146, 148:

> * * * the language of [the third paragraph of] Section 112 is thought to be so clear as not to require any resort to extrinsic evidence in connection with its interpretation.

The board also noted (at p. 148) that:

> * * * some measure of greater liberality in the use of functional expressions in the definition of elements in proper combination claims is authorized by Section 112, than has been permitted by some of the stricter decisions of the courts in the past.

Inasmuch as it is our opinion (1) that there is no statutory ban on the use of the "functional" language employed in the instant claims by appellant; (2) that cases cited in support of the Patent Office's condemnation of the statements of function used in the instant claims are inapplicable to the situation here; (3) that the use of such functional statements as here appear is specifically sanctioned by the third paragraph of 35 U.S.C. 112; and (4) that no objection has been made to the sufficiency of appellant's invention description to support in nonfunctional terms the functional statements made in the claims, we reverse the rejection of the instant claims as functional.

(b) Undue Breadth

The rejection of the claims for "undue breadth" places particular emphasis on (1) an alleged "undue burden upon the public *to determine* what salts are *suitable* for obtaining the desired results" (emphasis ours), and (2) an alleged "undue [amount of] experimentation"

required of those skilled in the art to determine those salts possessing the "function asserted" by the instant claims. The undue breadth rejection phase of the instant case appears in the following posture. Appellant has *described* his invention as *comprehending* the use therein of *any* inorganic salt *capable* of performing a *specific* function in a specific combination and he has disclosed specifically four such salts which are capable of performing this function. The examiner and the board, believing that not all inorganic salts are capable of performing this function and that one skilled in the art would not know offhand which inorganic salts are capable of so functioning, have rejected the claims as "unduly broad."

It is clear that the instant claims do not comprehend a class of inorganic salts of any greater breadth than is *comprehended* by the invention description. [12] It is equally clear from this description and appellant's brief that, in the words of the *second* paragraph of section 112, "applicant regards as his invention" the combination with his other tread ingredients of *any* inorganic salt *capable* of "maintaining the carbohydrate, the protein, or mixture thereof, in colloidal suspension * * *." It is exactly this combination which appellant has particularly pointed out and *distinctly claimed* in compliance with the *second* paragraph of section 112. If, therefore, as the examiner alleges, many an "inorganic salt * * * would not be operative for appellant's purpose," this criticism bears only on the sufficiency of the invention description. But its adequacy under the *first* paragraph of section 112 has not been questioned.

[8] We find the arguments of the board and the examiner relating to experimentation necessary to determine the suitability of *undisclosed* salts to operate in appellant's claimed combination beside the point. Appellant's invention is the *combination* claimed and not the discovery that certain inorganic salts have colloid suspending properties. We see nothing in patent law which requires appellant to discover which of all those salts have such properties and which will function properly in his combination. The invention description clearly indicates that any inorganic salt which has such properties is usable in his combination. If others in the future discover what inorganic salts additional to those enumerated do have such properties, it is clear appellant will have no control over them per se, and equally clear his claims should not be so restricted that they can be avoided merely by using some inorganic salt not named by appellant in his disclosure. The only "undue burden" which is apparent to us in the instant case is that which the Patent Office has attempted to place on the appellant. The Patent Office would require him to do research on the "literally thousands" of inorganic salts and determine which of these are suitable for incorporation into his claimed combination, apparently forgetting that he has not invented, and is not claiming colloid suspending agents but tire tread stock composed of a combination of rubber and other ingredients.

We are not persuaded that our conclusion on this point is wrong by decisions of this and other courts relating to the sufficiency of invention disclosures in cases wherein the applicant is claiming chemical *compounds* per se.

The Patent Office rejections of claims 38-49 are *reversed.*

Footnotes

Footnote 1. Appellant discloses what "inorganic salts" are suitable in the following manner:

> I also add to the rubber stock one or more inorganic salts which are effective in maintaining the carbohydrate, the protein, or mixture thereof, in colloidal suspension in the film of water which surrounds the tire when it engages a wet or icy road or pavement. For this purpose, I may utilize a sodium salt, such as sodium carbonate, tri-calcium phosphate, magnesium carbonate or calcium carbonate.

Footnote 2. The operation of appellant's tire stock to achieve its intended purpose is described as follows:

> * * * slipping or skidding of the tire will * * * produce wear upon the tire and a small amount of the carbohydrate or protein, or a mixture thereof, will form a colloidal suspension in the film of water and will be maintained in colloidal suspension therein by the inorganic salt which is present, thereby reducing the lubricating properties of the film of water to thus provide good traction between the tire and the road or pavement on which it is being driven.

Footnote 3. Reference to the use of (1) a protein *and* a carbohydrate is made in claims 38, 39, 44, and 45; (2) only a carbohydrate in claims 40, 41, 46, and 47; and (3) only a protein in claims 42, 43, 48, and 49. We disregard these differences in the claims inasmuch as appellant has not attached any significance thereto.

Footnote 4. Claims 38, 40, 42, 44, 46, and 48 designate the lower limit of the added carbohydrate and/or protein as being of "more than incidental" amount--claims 39, 41, 43, 45, 47, and 49 set this lower limit at 5% by weight of the rubber tread stock. Because of the 5% limitation in the latter claims, only the former have been rejected as indefinite and ambiguous.

Footnote 5. See note 4, supra.

Footnote 6. Davis et al., "Chemistry and Technology of Rubber", published by Reinhold Publishing Corporation, 1937, pages 18, 20, 26, 27 and 53. The examiner's reliance on Davis et al., a reference newly cited in his answer, was based on the premise that claims which "merely recite a stock which includes rubber, a protein and/or a carbohydrate, and an inorganic salt while the specification, at pages 7 and 8, teaches that the alleged invention lies in adding the protein and/or carbohydrate and the inorganic salt to a rubber stock" do not distinguish over "natural rubber." Appellant thereupon amended the instant claims to state that the nonadhesive protein and/or carbohydrate in his tire tread stock were "in addition to" such substances which might occur in "the base portion" of the stock. The examiner, thereupon, considered as "overcome" that portion of his answer which relied on Davis et al.

Footnote 7. [2] If support need be cited for this, see Robinson on Patents, Vol. II, particularly at § 483 (pp. 72-73) and § 504 (pp. 110-111). Also, 35 U.S.C. 112 clearly indicates, in its *first* paragraph, that it is the function of the "written description" of the invention to "enable" one skilled in the pertinent art to "make and use" the invention, and, in its *second* paragraph, that the claims have a separate and distinctive function, namely, particularly to point out and distinctly claim what "applicant regards as his invention."

Both the invention description and the claims form parts of a patent application's "specification." 35 U.S.C. 112. However, inasmuch as the remainder of this opinion deals to some extent with the problem of analyzing the relationship that exists between the invention description and the claims, the word "specification" will not be used.

Footnote 8. The third paragraph of 35 U.S.C. 112 reads:

> *An element* in a claim *for a combination* may be expressed as a means or step for performing a specified function without the recital of structure material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. [Emphasis ours.]

Footnote 9. One of the primary problems we have in coming to grips with the instant rejection is in what sense the word "functional" is being used. Few words in patent law have acquired more diverse meanings than the word "functional." Ellis, for example, in his "Patent Claims" (1949) at § § 255-276 discusses at least five. It is for this reason that bandying about and lifting out of context statements referring to "functional" expressions, has, as Ellis euphemistically puts it, "caused confusion." In addition to Ellis, supra, some of the more recent texts which outline the confusion that exists in the case law with regard to what are "functional" statements, and how they should be treated, are: Glascock and Stringham, Patent Law, pp. 315-324 (1943); Hoar, Patent Tactics and Law, pp. 116-118 (3rd ed., 1950); Stringham Patent Claim Drafting, pp. 215-243 (1950); Deller's Walker on Patents, particularly at § 168 (as supplemented to 1962).

Footnote 10. This statement, if correct, would lead appellant into somewhat of an impasse--statements indicating what an entity is "supposed to do" *as well as* statements indicating what that entity "does" may *both* be "functional."

Footnote 11. We do not mean to imply that 35 U.S.C. 112 was not in derogation of the result reached in *any* case decided prior to the enactment of the 1952 Patent Act. See, e.g., Halliburton Oil Well Cementing Co. v. Walker et al., 329 U.S. 1, 71 USPQ 175. We feel, however, that a considerable body of case law, if not the preponderance thereof, before the Halliburton case interpreted broad statements of structure, e.g., "means," plus a statement of function in the manner now sanctioned by the statute. See, e.g., Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 558. See also in this regard the February 1952 issue of the American Patent Law Association Bulletin wherein is reprinted at pp. 40-50 an address by the Hon. JosephR. Bryson, Representative from South Carolina, given on January 24, 1952, to the Philadelphia Patent Law Association. Representative Bryson was at this time Chairman of Subcommittee No. 3 of the Judiciary Committee of the House of Representatives, which subcommittee was in charge of the legislation which resulted in the Patent Act of 1952. He stated in part (at pp. 45-46):

> I should like to say a word on the provision in the bill for functional claiming. [H.R. 3760, 82d Cong., 1st Sess., § 112 (1951)] * * *. This provision in reality will give statutory sanction to combination claiming as it was understood before the Halliburton decision. *All the elements of a combination now will be able to be claimed in terms of what they do as well as in terms of what they are.* [Emphasis ours.]

For a more complete analysis of the cases under the third paragraph of 35 U.S.C. 112 since its enactment, see Woodcock, "Patent Act of 1952--Ten Years of Interpretation: Section 112," p. 157, American Bar Association Section of Patent, Trademark and Copyright Law, Summary of Proceedings at San Francisco, California (1962).

Footnote 12. See note 1, supra.

Concurring Opinion Text

Concur By:
MARTIN, Judge, concurs in result only.

Dissenting Opinion Text

Dissent By:
WORLEY, Chief Judge, dissenting, with whom ALMOND, Judge, joins.

I am unable to agree that the board erred in rejecting the claims on the grounds of functionality and undue breadth.

Appellant defines one of the materials in his composition as *"an inorganic salt* that is *capable of holding a mixture* of said carbohydrate and protein *in colloidal suspension* in water." (Italics supplied.) The examiner held that language failed to properly define the invention.

In affirming, the board stated:

> * * * *There is no indication that the function asserted for the salts is known in the art so that the suitable salts could be readily* determined without undue experimentation *nor is there any criteria given in the disclosure by which it could be fairly readily determined what salts are suitable.* It seems that *the determination of suitable salts thus would require testing by trial and error many thousands of known salts to ascertain those which would function in the manner required by the claims,* and such a burden should not be required of the public or even by those skilled in the art. Accordingly, we will sustain this rejection. (Italics supplied.)

I find no evidence in the record before us which would in anywise refute that reasoning and conclusion.

The basis for rejection here is clearly 35 U.S.C. 112 which requires an applicant to particularly point out and distinctly claim his alleged invention. The issue of failure to comply with that section because of functionality introduces an element of degree, which, much like

the question of obviousness, is dependent on the particular facts in each case.

It seems to me that one skilled in this art would be unable to determine, without elaborate experimentation, which salts, other than the four disclosed, are capable of performing the desired function. That is so because appellant has failed to disclose any factual criteria or scientific principles upon which equivalence can be based.

Only four examples are given in the specification and they belong to a narrow group, viz, alkaline earth or alkali salts of carbonic or phosphoric acid. The disclosure does not teach whether *any* inorganic salts, other than the four disclosed, would perform the same function. The common properties of the salts relied on to perform said function are *not* disclosed, nor are the examples sufficiently numerous to make clear what those properties might be. Since equivalent salts cannot be determined from the teaching of the disclosure or the skill of the art, surely appellant is not entitled to claim them. Discovery of suitable salts would seem to require not merely determining whether they would keep the protein and carbohydrate in colloidal suspension in a laboratory test tube, but whether they would actually maintain the suspension under conditions of use, i.e., in icy water, under the pressure of a rotating automobile tire, and for a sufficient length of time.

The claims employ functional terminology which clearly results in their being vague, indefinite and too broad. As such their allowance is precluded by 35 U.S.C. 112. I would affirm.

- End of Case -

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